

### **DETAILED ACTION**

*The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 25 June 2009.*

#### ***Priority***

This application claims benefit as a 371 of PCT/EP04/04001 (filed 04/13/2004) and from foreign application UNITED KINGDOM 0308696.4 (filed 04/15/2003). The instant application has been granted the benefit date, 15 April 2003, from foreign application UNITED KINGDOM 0308696.4.

### **RESPONSE TO ARGUMENTS**

#### ***35 USC § 112, 2<sup>nd</sup>***

The rejection of claims 1-2 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in response to the applicants arguments and/or claim amendments.

The applicant's arguments have been fully considered and are persuasive. The applicant has amended the claims so that the term "relevant" has been removed from the pending claims.

Therefore, the examiner hereby withdraws the rejection of claims 1-2 under 35 USC 112, 2<sup>nd</sup> paragraph.

**35 USC § 112, 1<sup>st</sup>**

The rejection of claims 1-2 under 35 USC 112, 1<sup>st</sup> paragraph (lack of enablement) is withdrawn in response to the applicant's arguments and/or claim amendments.

The applicant's arguments have been fully considered and are persuasive. The applicant has amended the claims so that the claimed mutant microorganisms contain disrupted 5S clavum biosynthesis gene such that clavulanic acid production is at least maintained "when compared to the parent strain which has not had such disruptions."

In addition, the applicant has presented several arguments:

The applicant pointed out that the examiner has confused the various names of the paralogous genes, presented by the applicant and the cited art. The examiner apologizes for this confusion.

The applicant also persuasively argues that the same growth trends are found in different media for the various mutants. This part of the examiner's argument is withdrawn.

Therefore, the examiner hereby withdraws the rejection of claims 1-2 under 35 USC 112, 1<sup>st</sup> paragraph (lack of enablement).

***Examiner's amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrea Lockenour on 7/8/2009.

The claims have been amended as follows:

1. (Currently Amended) An isolated *S. clavuligerus* microorganism comprising DNA from which SEQ ID NO:1 has been disrupted or deleted such that the production of 5S clavams by said *S. clavuligerus* is reduced and clavulanic acid production is at least maintained when compared with a *S. clavuligerus* comprising SEQ ID NO:1 which has not been disrupted or deleted.
  
- 2 (Currently Amended) An isolated *S. clavuligerus* microorganism comprising DNA from which SEQ ID NO:1 and one or more of: SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:10, and SEQ ID NO:11 have been disrupted or deleted such that the production of 5S clavams by said *S. clavuligerus* is reduced and clavulanic acid production is at least maintained when compared with a *S. clavuligerus* which has not had said open reading frames disrupted or deleted.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The prosecution history provides evidence for allowability.

Therefore, the instant claims are free of prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 1-2 are allowed. Claims 3-20 have been cancelled.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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